

**REMARKS/ARGUMENTS**

Reconsideration and allowance of the above-referenced application are respectfully requested.

In accordance with the Examiner's request the priority applications cited on page 1 of the subject application have been updated in order to reflect current status.

Claims 1 and 5 have been cancelled, and claims 2-4 have been amended.

Additionally, Applicants have addressed the Examiner's objection to claim 4, subsection (c) via amendment.

**Rejection of Claims 1, 2 and 5 Under 35 U.S.C. 112, Second Paragraph**

The Examiner has contended that claims 1, 2, and 5 are vague and indefinite since they do not reference the breast cancer markers with identifying SEQ ID numbers.

In response, it is submitted that this rejection has been obviated by the recitation in claim 2 (claim 1 and 5 having been cancelled) of sequence identifier numbers corresponding to BU101, gammaglobin and BS106. It is not possible to provide a precise sequence identifier number in connection with multimeric polypeptide antigen.

The Examiner has additionally indicated that claims 1 and 2 are vague and Indefinite because they recite incomplete method steps. In particular, the Examiner contends that the diagnostic tool utilized is not specified.

In response, Applicants submit that it is irrelevant how the combination of polypeptides is detected (i.e., via antibody complex, conjugate, etc.). Any diagnostic method known to one of ordinary skill in the art may be utilized provided such method allows one to detect the presence or absence of both polypeptides of the combination. Thus, it is respectfully submitted that this rejection has been overcome.

In view of the above, it is submitted that the Section 112, second paragraph rejection of claims 1, 2, and 5 (now claim 2) has been overcome and should be withdrawn accordingly.

Rejection of Claims 1-5 Under 35 U.S.C. 102(b)

The Examiner has rejected claims 1-5 (now claims 2-4) under Section 102(b) as being anticipated by WO 98/21331. In particular, the Examiner contends that the documents disclose Applicants' mammaglobin and BU101 polypeptides, which are the same as human steroid-binding protein, hSBP2 and hSBP1. Further, the Examiner alleges that the abstracts state that hSBP1 and hSBP2 are used in methods of diagnosis and monitoring breast cancer.

In response, Applicants submit that the cited document does not disclose detection of the presently claimed combinations of markers in the diagnosis of breast cancer (i.e., (1) BS106 and BU101, (2) BS106 and mammaglobin and (3) BS106 and MPA). Again, the emphasis of the present invention is that the presence of each member of each combination, not simply presence of one marker, correlates with breast cancer diagnosis. This concept is not taught or disclosed in the cited reference.

It is submitted that the Section 102(b) rejection of claims 1-5 (now claims 2-4) has been overcome and should be withdrawn accordingly.

Rejection of Claims 1-5 Under 35 U.S.C. 102(e)

The Examiner has rejected claims 1-5 (now claims 2, 3 and 4) under Section 102(e) as being anticipated by U.S. patent application publication US 2003/0059432. In particular, the Examiner contends that the publication discloses Applicants' mammaglobin and BU101 polypeptides which are the same as lipophilin-like protein,

mammaglobin and lipophilin B. Further, the Examiner alleges that the document discloses diagnostic method assays for the presence or absence of a cancer in a patient which may comprises two antibodies, using a biological sample from a patient.

In response, Applicants again submit that the cited document does not disclose detection of the presently claimed combinations of markers in the diagnosis of breast cancer (i.e., (1) BS106 and BU101, (2) BS106 and mammaglobin and (3) BS106 and MPA). To reiterate, the emphasis of the present invention is that the presence of each polypeptide member of each combination, not simply presence of one marker, correlates with breast cancer diagnosis. This concept is not taught or disclosed in the cited reference.

In view of the above, it is submitted that the Section 102(e) rejection of claims 1-5 (now claims 2-4) has been overcome and should be withdrawn accordingly.

In conclusion, it is believed that the subject application is in condition of allowance and Notice to that effect is respectfully requested.

Should the Examiner have any questions concerning the above, she is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,  
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